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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/634,078

08/04/2003

Carl P. Decicco

PH-7477-NP

5245

23914

7590

10/30/2008

LOUIS J. WILLE

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PATENT DEPARTMENT

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EXAMINER

ROYDS, LESLIE A

ART UNIT

PAPER NUMBER

1614

NOTIFICATION DATE

DELIVERY MODE

10/30/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@BMS.COM

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Office Action Summary	Application No. 10/634,078	Applicant(s) DECICCO ET AL.	
	Examiner Leslie A. Royds	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09 Oct 03</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION**Claims 1-9 are presented for examination.**

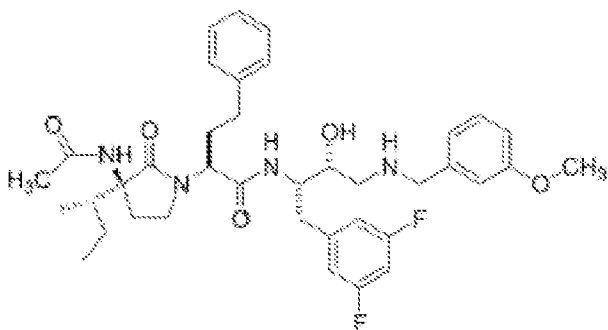
Acknowledgement is made of Applicant's claims for benefit under 35 U.S.C. 119(e) to U.S. Provisional Patent Application No. 60/401,390, filed August 5, 2002.

Applicant's Information Disclosure Statement (IDS) filed October 9, 2003 has been received and entered into the present application. As reflected by the attached, completed copies of form PTO-1449 (two pages total), the Examiner has considered the cited references.

Applicant's response filed January 30, 2008 to the requirement for restriction/election dated January 15, 2008 has been received and entered into the present application. Pursuant to the notice dated April 17, 2008, Applicant's response dated January 30, 2008 was non-compliant. Applicant's response filed July 2, 2008 correcting the deficiencies set forth in the notice dated April 17, 2008 has been received and entered into the present application.

Requirement for Restriction/Election

Applicant's election **without traverse** of the invention of Group I (claims 1-7), directed to compounds of formula (I) or a stereoisomer or pharmaceutically acceptable salt thereof and a pharmaceutical composition thereof, and election of species of the compound (2S)-2-(3(S)-acetylamino-3-((S)-sec-butyl-2-oxo-pyrrolidin-1-yl)-N-[(1S,2R)-1-(3,5-difluoro-benzyl)-2-hydroxy-3-(3-methoxy-benzylamino)-propyl]-4-phenyl-butyramide of the structure:



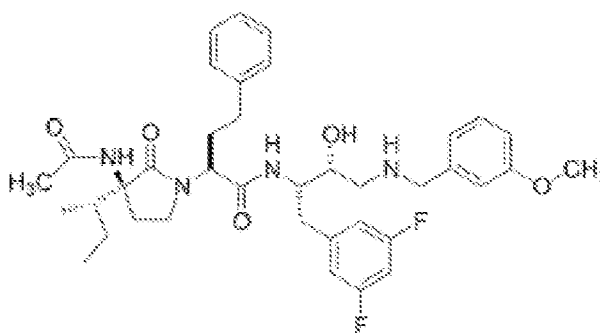
for examination on the merits, in the reply filed

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July 2, 2008, is acknowledged by the Examiner.

Examination of the Instant Claims

Search and examination of the instant claims was performed insofar as the instant claims read upon the elected species of (2S)-2-(3(S)-acetylamino-3-((S)-sec-butyl)-2-oxo-pyrrolidin-1-yl)-N-[(1S,2R)-1-(3,5-difluoro-benzyl)-2-hydroxy-3-(3-methoxy-benzylamino)-propyl]-4-phenyl-butyramide



with the chemical structure of _____ as set forth in the reply filed July 2, 2008. A reasonable and comprehensive search determined that the prior art at the time of the invention was such that it did not anticipate or render obvious the elected specie of (2S)-2-(3(S)-acetylamino-3-((S)-sec-butyl)-2-oxo-pyrrolidin-1-yl)-N-[(1S,2R)-1-(3,5-difluoro-benzyl)-2-hydroxy-3-(3-methoxy-benzylamino)-propyl]-4-phenyl-butyramide.

Accordingly, search and examination was expanded to cover the full scope of compounds instantly claimed and it was again determined that the prior art at the time of the invention was such that it did not anticipate or render obvious the genus of compounds instantly claimed. As a result, Applicant's product claims (i.e., claims to compounds and pharmaceutical compositions thereof) appear, at this time, to be in condition for allowance. In accordance with the rejoinder practice described at page 7 of the Office Action dated January 15, 2008, Applicant's instant claims 8-9, directed to a method of using the compounds of instant claim 1, have been rejoined with claims 1-7 due to the fact that they are strictly commensurate in scope with the compounds that have been determined to be allowable. Claims 1-9 are under examination and are in condition for allowance at this time.

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EX PARTE QUAYLE ACTION

This application is in condition for allowance at this time except for the following formal matters:

Objections to the Specification

(1) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). *See e.g.*, p.128, 1.2-3 and 12 and p.131, 1.5 and 57 of the specification. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825, because it lacks any submission of a computer readable form sequence listing, a paper copy for the specification, a statements under 37 CFR §§ 1.821(f) and (g), and SEQ ID Nos. cited along with each sequence in the specification or figures.

Applicant is reminded that SEQ ID Nos. are not required in figures, *per se*. However, the corresponding SEQ ID Nos. are required in the Brief Description of the Drawings section in the specification. Applicant is also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies.

The paper or compact disc copy of the Sequence Listing is an integral part of the application. If submitted on paper, the Sequence Listing must begin on a new page, should appear at the end of the application, and preferably should be numbered independently of the numbering of the remainder of the application. The new page that begins the "Sequence Listing" should be entitled "Sequence Listing." If not submitted as such at filing, the Sequence Listing must be inserted into the application *via* amendment, *e.g.*, by preliminary amendment. If submitted on compact disc, the specification must contain an incorporation by reference of the material on the compact disc in a separate paragraph, identifying each compact disc.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

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A shortened statutory period for reply to this action is set to expire TWO (2) MONTHS from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

October 21, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614